

### **REMARKS/ARGUMENTS**

Claims 1, 6, 9, 10, 13 and 14 are pending in the present application. In the Office Action, the Examiner rejects claims 1, 6, 9, 10, and 13 under the doctrine of obviousness-type double patenting over claim 1 of US Patent No. 7,247,620 in view of US Patent No. 6,406,456. The same claims are rejected under 35 U.S.C. § 103(a) for allegedly being obvious over Nakanishi *et al.* (2002) in view of the '456 patent. Claims 13 and 14 stand rejected over Nakanishi and the '456 patent further in view of Yamamoto *et al.* (1996), Gaine (2000), and Ullrich *et al.* (2001). Each of these rejections is addressed below.

#### **Obviousness-Type Double Patenting Rejection**

The rejection of claims 1, 6, 9, 10, and 13 over claim 1 of the '620 patent in view of the '456 patent is respectfully traversed. According to the Examiner claim 1 of the '620 patent encompasses "methods of treating wounded skin using a nucleic acid sequence encoding hepatocyte growth factor (HGF)." This claim is not limited to a particular manner of administration of the nucleic acid. The '456 patent is cited for teaching the use of needleless syringes to deliver a fluid medicament. This patent does not disclose the or suggest the specific administration route for delivery of a polynucleotides as claimed here. Further, this patent provides no evidence regarding the ability to administer nucleic acids for gene therapy by needleless injection. The Examiner asserts that it would have been obvious to use the needleless syringe taught in the '456 patent in the method claimed in the '620 patent.

It is well settled that an obviousness-type double patent rejection parallels the analysis of obviousness under 35 U.S.C. § 103(a) (MPEP §804.B.1). Section 2141 of the MPEP sets forth examination guidelines for determining obviousness under §103(a). As noted there, a rejection for obviousness can be overcome by a showing that the invention provides unexpected or surprising results.

Example 2 of the present specification provides objective evidence that needleless injection of polynucleotides encoding a marker gene (luciferase) is 100 times more effective than prior art needle injection. Moreover Example 3 describes experiments in which HGF (with or

without injection of the prostacyclin synthetase (PGIS) gene) was shown to accelerate wound healing and enhance blood flow within four days of wound creation.

Thus, although claim 1 of the '620 patent covers a broad range of methods of administering polynucleotides encoding HGF, the present invention provides evidence that use of needleless syringe to administer the polynucleotides is a surprisingly effective means for treating skin disorders. Withdrawal of the double patenting rejection is respectfully requested.

**Rejection under 35 U.S.C. § 103(a)**

The rejection of claims 1, 6, 9, 10, and 13 over Nakanishi *et al.* (2002) in view of the '456 patent is respectfully traversed. According to the Examiner, Nakanishi *et al.* teach the administration of an expression vector encoding HGF in combination with HVJ liposomes using a syringe. The Examiner acknowledges that needleless syringes are not taught in this reference. The Examiner sites the '456 patent for the missing teaching.

As noted above, an obviousness rejection can be overcome by a showing that the claimed invention provides unexpected or surprising results. As shown above, the present specification provides objective evidence that needleless injection is a surprisingly effective means for treating skin disorders. The rejection is therefore improper and should be withdrawn.

The rejection of claims 13 and 14 over Nakanishi and the '456 patent further in view of Yamamoto *et al.* (1996), Gaine (2000), and Ullrich *et al.* (2001) is respectfully traversed. Claims 13 and 14 are directed to the administration of HGF, PGIS or combination of HGF and PGIS. Yamamoto *et al.* is cited for allegedly teaching treatment of skin disorders using a prostacyclin analog (PGI<sub>2</sub>), Gaine is cited for allegedly that genes encoding PGIS can be used in place of prostacyclin analogs. Ullrich is cited for teaching the pathway by which prostacyclin is produced *in vivo*.

As noted above, the primary references provide no evidence that a needleless syringe is a surprisingly effective means to administer polynucleotides. None of the secondary references (Yamamoto *et al.*, Gaine or Ullrich *et al.*) address this deficiency. Indeed, none of the cited references provide any evidence that administration of a gene encoding PGIS around a

wound site would have any effect on wound healing. In view of the above, applicants respectfully submit the rejection is improper and should be withdrawn.

**CONCLUSION**

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested. If a telephone conference would expedite prosecution of this application, the Examiner is invited to telephone the undersigned at 415-576-0200.

Respectfully submitted,

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